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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,092	06/15/2005	Robert Petermann	112701-626	9222

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EXAMINER	
DEES, NIKKI H	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
06/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,092	PETERMANN ET AL.	
	Examiner	Art Unit	
	Nikki H. Dees	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed February 29, 2008, has been entered. Previously presented claims 1-12 and new claim 13 remain pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 13 claims the nutritional formula comprising 0.5-3.5 % L-(+) lactic acid. It is unclear what this percentage is based upon (e.g. weight or volume) as well as whether it is a percentage in the initial powdered product or in the final liquid state.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, 7-12 and new claim 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer et al. (WO 96/31130) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539).

7. Mazer et al. teach a nutritional formula providing calcium. The nutritional formula may be either a dry powder or liquid (p. 9). The nutritional formula is in the form of beverages having a pH of less than 4.6 (p. 10). Purified lactic acid is used as an acidulant in the beverages and beverage concentrate (p. 34). The direct addition of lactic acid may be used to further adjust the pH of the beverage concentrate (p. 42). Lactic acid is taught in Tables 19-21 at 0.391 wt % of the final liquid beverage product.

8. Mazer et al. teach sweeteners to be used in their invention, including sucrose, fructose, glucose and lactose (pp. 34-35). The use of one or more of these sweeteners would serve as a source of carbohydrates in the beverage.

9. A method of preparing the nutritional formula is taught in Example 2 (p. 42). A carbohydrate source (used in place of aspartame) is hydrated. The lactic acid is added prior to the sweetener. A lipid source (partially hydrogenated soybean oil) is present in the vitamin D3 emulsion (p. 33). This emulsion is added to the blend of sweetener and lactic acid.

10. Regarding claim 9 and the order of mixing the ingredients, the selection of any order of mixing ingredients is *prima facie* obvious. See *In re Gibson*, 39 F.2d 975,5 USPQ 230 (CCPA 1930). It would have been obvious to one of ordinary skill in the art

at the time the invention was made that the order of addition of the ingredients in the beverage taught by Mazer et al. may be altered without having an adverse effect on the resulting beverage product.

11. Regarding claim 11, Mazer et al. teach that acidity is desired in the liquid nutritional product for several reasons, including controlling microbial growth (p. 13).

12. Regarding claim 13, one of ordinary skill would have been able to adjust the amount of lactic acid contained in the invention in order to provide an invention with desirable acidity as well as a desirable flavor. The adjustment of the amount of lactic acid would have been well within the abilities of one of ordinary skill and there would have been a reasonable expectation that the lactic acid would have functioned as desired in providing the desired taste as well as function as a preservative.

13. Mazer et al. are silent as to the use of L (+) - lactic acid in their beverage.

14. The WHO teaches that (DL) - lactic acid and D (-) - lactic acid should not be used in infant foods. This leaves only L (+) - lactic acid for use in infant foods.

15. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized greater than 70% by weight L (+) - lactic acid in the beverage taught by Mazer et al in order to result in a beverage that may be marketed to the widest possible audience, including infants.

16. Claims 1, 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO

(Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

17. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

18. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

19. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

20. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

21. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

23. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the

pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

24. Claims 1, 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

25. Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

26. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

27. Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

28. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

29. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by

Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

Response to Arguments

30. Applicant's arguments filed February 29, 2008, have been fully considered but they are not persuasive.

31. With regard to the 103 rejection of claims 1, 2, and 7-12 over Mazer in view of WHO, Applicant argues (Remarks, p. 4) that Mazer fails to disclose a formula directly acidified with L(+) lactic acid. Applicant further argues (Remarks, p. 4) that the lactic acid of Mazer is a fermented lactic acid.

32. In response, the examiner notes that Mazer teaches the use of lactic acid (88%) for use in the invention (Tables 18-21, for example). One of ordinary skill in the art would recognize that lactic acid 88% would be a product such as PURAC FCC 88 comprising L(+) lactic acid produced by fermentation. The product of Mazer itself is not fermented. It is noted that PURAC FCC 50 is a lactic acid material disclosed by Applicants (specification p. 13, lines 18-20) for use in their invention. PURAC FCC 50 is also L(+) lactic acid produced by fermentation. Mazer, like Applicants, avoids a fermentation step in the production of their powdered beverage comprising lactic acid. The beverage of Mazer is directly acidified by the addition of lactic acid.

33. Applicant argues (Remarks p. 5) that WHO teaches away from using L-(+) lactic acid in nutritional compositions.

34. The examiner notes that the WHO document specifically states that neither D-(-) or (DL) lactic acid should be used in infant foods. The examiner reasserts the position that this leaves only L-(+) lactic acid for use in infant foods. One of ordinary skill would further recognize that food-grade lactic acids available are primarily L-(+) lactic acids, as indicated by the PURAC product literature. Therefore, one of ordinary skill would have had reason to utilize L-(+) lactic acid in the invention of Mazer in view of the WHO.

35. With regard to the 103 rejection of claims 1, 3-6 and 12 over Schwartz in view of WHO, Applicant argues that the references are not combinable (Remarks, p. 6). Applicant further argues (Remarks, p. 6) that WHO fails to disclose a formula for direct acidification using L(+) lactic acid, fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

36. Applicant provides no support for the argument that the references are not combinable. However, in response the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill looking to the teachings of Schwartz for the production of lactic acid milk would look to the teachings of the WHO for the type of lactic acid to be used in the formula. Schwartz teaches USP lactic acid for use in his invention. However, it is

unclear which enantiomers make up the USP lactic acid of his invention. The WHO teaches that D-(-) and DL -lactic acid are not appropriate for use in infant formulas. One of ordinary skill would recognize that L-(+) lactic acid the obvious choice for inclusion in the infant formula. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature. Wong is used for support to show that milk contains the proteins and carbohydrates as claimed by Applicants. Therefore, the combination of the references renders Applicant's claims obvious.

37. With regard to the 103 rejection of claims 1, 3-6 and 12 over Takahata in view of WHO, Applicant again argues that the references are not combinable (Remarks, p. 6). Applicant further argues (Remarks, p. 7) that WHO fails to disclose a formula for direct acidification using L(+) lactic acid, fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

38. Applicant provides no support for the argument that the references are not combinable. However, in response the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill looking to the teachings of Takahata for the production a milk

beverage acidified with lactic acid would look to the teachings of the WHO for the type of lactic acid to be used in the beverage. The WHO teaches that D-(-) and DL lactic acid are not appropriate for use in infant formulas. One of ordinary skill would recognize that only L-(+) lactic acid is left for use. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L-(+) as evidenced by PURAC literature. Wong is used for support to show that milk contains the proteins and carbohydrates as claimed by Applicants. Therefore, the combination of the references renders Applicant's claims obvious.

Conclusion

39. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
Examiner
Art Unit 1794

/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794